Remarks

Claims 1-12 are pending in the present application. Claims 1, 2 and 6 are cited as allowable. Claims 8-12 are rejected under 35 USC 112, first paragraph. In addition, Claims 3-5 and 7-12 are rejected under 35 USC 112, second paragraph.

The pending claims have been amended to further clarify the claims, to recite the preferred use in Claim 11, and to expedite prosecution. No new matter has been added by this amendment.

The Examiner's rejections of objections and rejections of pending Claims 3-5 and 7-12 shall now be addressed in the order the rejections were made by the Examiner.

Rejection of Claims 8-11 Under 35 USC 112, First Paragraph

The Examiner rejected pending Claims 8-11 as failing to comply with the written description requirement. Specifically, the Examiner stated that the specification discloses a list of diseases or conditions that are mediated by inhibition of dipeptidyl peptidase-IV (hereinafter "DPP-IV"). The Examiner also stated that these are deemed speculations as no journal articles or biological assays were provided as evidence of this statement. However, the Examiner also stated that provision of evidence of such uses would overcome this rejection.

Claims 8-9, and 11

Claims 8-9, as amended, recite a method for treating a condition mediated by DPP-IV inhibition, wherein said condition is selected from the group consisting of Type 1 diabetes, Type 2 diabetes, metabolic syndrome, hyperglycemia, impaired glucose tolerance, diabetic neuropathy, diabetic nephropathy, diabetic retinopathy, diabetic cardiomyopathy, and obesity, in a mammal by administering to said mammal a therapeutically effective amount of a compound of Claim 1 or a pharmaceutical composition of Claims 2 or 3.

As suggested by the Examiner, Applicant is submitting herewith journal articles as evidence to demonstrate that the use of DPP-IV inhibitors to treat the conditions recited in Claims 8, 9 and 11, as amended, are not speculative. For instance, the use of DPP-IV inhibitors to treat insulin resistance (insulin resistance syndrome is also known as metabolic syndrome), Type 1 and Type 2 diabetes and glucose tolerance are disclosed in Regulatory Peptides 128 (2005) 159-165, by McIntosh et al. This reference also discloses the use of DPP-IV inhibitors to increase the level of circulating glucagon-

like peptide (hereinafter GLP-1) in mammals. In addition, the use of DPP-IV inhibitors to treat hyperglycemia is disclosed in J. Med. Chem. (2002), 45, 2362-2365. Further, Current Opinion in Clinical Nutrition and Metabolic Care (2005), 8(1), 9-16 discusses the use of increased GLP-1 levels to establish diabetic control in elderly patients, particularly those suffering from diabetic complications such as diabetic neuropathy, diabetic nephropathy, diabetic retinopathy and cardiovascular diseases. Furthermore, Horm. Metab. Res. (Nov-Dec 2004) 36(11-12), 852-8, states that antidiabetic amounts of GLP-1 suppress appetite, enhance satiety, and reduce food intake at the same time which will lead to weight loss.

Regarding Claim 10, as said claim is now cancelled, this rejection is moot.

Therefore, in view of the above, this rejection of Claims 8-11, for failure to comply with the written description requirement, should be withdrawn.

Rejection of Claim 12 Under 35 USC 112, First Paragraph

The Examiner has rejected pending Claim 12 as failing to comply with the written description requirement. Specifically, the Examiner stated that the specification fails to disclose the structural definitions of the "prodrug" of the compounds of Claim 1 so as to enable one of ordinary skill in the art to determine the structures of the compounds that are included and/or excluded by the term "prodrug".

The Examiner's rejection of Claim 12 for failure to meet the written description requirement is erroneous.

Claim 12 recites a prodrug of one of two compounds, (2S)-2-amino-2-cyclohexyl-1-((3RS)-3-fluoro-pyrrolidin-1-yl)-ethanone or (S)-2-amino-2-cyclohexyl-1-(3,3-difluoro-pyrrolidin-1-yl)-ethanone, or a pharmaceutically acceptable salt of said prodrug. In addition, a discussion of examples of suitable prodrugs, of these two compounds, is provided on Specification page 7, lines 2-12, such as the amino prodrugs N-acyl, N-carboalkyl and imine derivatives. Furthermore, in view of the limitation of Claim 12 to prodrugs of only two amino-containing compounds, or salts thereof, and in view of the teachings in the Specification, it is clear that the present Application reasonably conveys to those skilled in the art that the inventor had possession, at the time of filing, of the claimed invention.

Therefore, in view of the above, this rejection of Claim 12, for failure to comply with the written description requirement, is not proper and should be withdrawn.

Rejection of Claims 3-5 and 7-12 Under 35 USC 112, Second Paragraph

The Examiner has rejected pending Claims 3-5 and 7-12 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

Claims 8-11

The Examiner stated that Claims 8-11 are indefinite for the reasons set forth in the rejection of Claims 8-11 under 35 USC 112, first paragraph. However, under 35 USC 112, first paragraph, the Examiner rejected Claims 8-11 as failing to meet the written description requirement in stating that the conditions cited as treatable by administration of the compounds, of the invention, were speculative.

The Examiner's rejection of Claims 8-11 for indefiniteness is erroneous. The requirements of the first and second paragraphs of 35 U.S.C. 112 are separate and distinct. Argument by the Examiner that the claimed medical conditions, which can be treated by use of a compound, are speculative does not bear on the question of clarity or indefiniteness of the claim. The test for indefiniteness is whether one of ordinary skill in the art could determine the metes and bounds of the claim so as to understand how to avoid infringement.

Claim 7, as amended, clearly recites a method of inhibiting DPP-IV in a mammal comprising administering to said mammal in need of DPP-IV inhibition a therapeutically effective amount of a pharmaceutical composition of any one of claims 2 or 3. The meaning of each term recited in Claim 7 is apparent to one of ordinary skill in the art and the language of said claim particularly points out and distinctly claims the Applicant's invention. Specifically, Claim 7 clearly recites a claim to a method for inhibiting DPP-IV in a mammal in need thereof.

Claim 8, as amended, clearly recites a method of treating a condition in a mammal, wherein said condition is selected from the group consisting of Type 1 diabetes, Type 2 diabetes, metabolic syndrome, hyperglycemia, impaired glucose tolerance, diabetic neuropathy, diabetic nephropathy, diabetic retinopathy, diabetic cardiomyopathy, and obesity, comprising administering to said mammal in need of such treatment a therapeutically effective amount of a compound of claim 1 or a pharmaceutically acceptable salt thereof. The meaning of each term recited in Claim 8 is apparent to one of ordinary skill in the art and the language of said claim particularly points out and distinctly claims the Applicant's invention.

Claim 9, as amended, clearly recites a method of treating a condition in a mammal, wherein said condition is selected from the group consisting of Type 1 diabetes, Type 2 diabetes, metabolic syndrome, hyperglycemia, impaired glucose tolerance, diabetic neuropathy, diabetic nephropathy, diabetic retinopathy, diabetic cardiomyopathy, and obesity, comprising administering to said mammal in need of such treatment a therapeutically effective amount of a pharmaceutical composition of any one of claims 2 or 3. The meaning of each term recited in Claim 9 is apparent to one of ordinary skill in the art and the language of said claim particularly points out and distinctly claims the Applicant's invention.

As Claim 10 is now cancelled, this rejection is moot.

Claim 11, as amended, clearly recites a method of treating Type 2 diabetes in a mammal, comprising administering to said mammal in need of such treatment a therapeutically effective amount of a pharmaceutical composition of any one of claims 2 or 3. The meaning of each term recited in Claim 1 is apparent to one of ordinary skill in the art and the language of said claim particularly points out and distinctly claims the Applicant's invention.

Therefore, in view of the above, this rejection of Claims 8-11, for lack of indefiniteness, is not proper and should be withdrawn.

Claim 12

The Examiner stated that Claim 12 is indefinite for the reasons set forth in the rejection of Claims 8-12 under 35 USC 112, first paragraph. However, under 35 USC 112, first paragraph, the Examiner rejected Claim 12 stating that the Specification fails to disclose the structural definitions of the "prodrug" of the compounds of Claim 1.

The Examiner's rejection of Claim 12 for indefiniteness is erroneous. Claim 12 clearly recites a prodrug of one of two compounds, (2S)-2-amino-2-cyclohexyl-1-((3RS)-3-fluoro-pyrrolidin-1-yl)-ethanone or (S)-2-amino-2-cyclohexyl-1-(3,3-difluoro-pyrrolidin-1-yl)-ethanone, or a pharmaceutically acceptable salt of said prodrug. The meaning of each term recited in Claim 1 is apparent to one of ordinary skill in the art and the language of said claim particularly points out and distinctly claims the Applicant's invention.

Therefore, in view of the above, this rejection of Claim 12, for lack of indefiniteness, is not proper and should be withdrawn.

Claim 4

The Examiner stated that Claims 3 and 4 are duplicates as the pharmaceutical composition of Claim 3 inherently has a pharmaceutical carrier or a diluent.

In response thereto, Claim 4 is now cancelled. Therefore, this rejection is moot and should be withdrawn.

Claims 7 and 9

The Examiner stated that Claims 7 and 9 are indefinite as they depend from Claim 4. Claims 7 and 9 are now amended as suggested by the Examiner. Therefore, this rejection is moot and should be withdrawn.

Claim 3

The Examiner stated that Claim 3 is confusing as it is not clear if the compounds have other non-essential elements. The Examiner further stated that the specification contains no support for the inclusion of non-essential elements. The Examiner concluded that these claims should be amended to stipulate that the compounds are selected from the list of compounds.

The Examiner's statement about lack of clarity is erroneous.

Claim 3 recites a pharmaceutical composition comprising a compound of Claim 1, or salt thereof, and a second compound. As the Examiner stipulated in the rejection of Claim 4, in reciting in the claim the phraseology "pharmaceutical composition", the claim implies inherently that said pharmaceutical composition has a pharmaceutical carrier or a diluent. Further, in Specification page 13, line 12, through page 14, line 22, suitable pharmaceutical compositions, for administering compounds of the present invention, are discussed.

However, Claim 3 has been amended to even more clearly recite that the pharmaceutical composition of Claim 3 comprises (a) a first dosage form comprising a compound of Claim 1, or a pharmaceutically-acceptable salt thereof, (b) a second dosage form comprising a second compound selected from a recited list, and inherently (c) other optional elements of said pharmaceutical composition.

Therefore, in view of the above, this rejection of Claim 3, for lack of clarity, is not proper and should be withdrawn.

Claim 5

The Examiner stated that Claim 5 is confusing as it is not clear if the compounds have other non-essential elements. The Examiner further stated that the specification contains no support for the inclusion of non-essential elements. The Examiner concluded that these claims should be amended to stipulate that the compounds are selected from the list of compounds.

The Examiner's statement about lack of clarity is erroneous.

Claim 5 recites a kit comprising (a) a first dosage form comprising a compound of claim 1, or a pharmaceutically acceptable salt thereof; (b) a second dosage form comprising a second compound, or pharmaceutically acceptable salt thereof, and (c) a container.

Further, Specification page 14, line 26, through page 15, line 5, states that the "kit comprises two separate compositions, a first dosage form that includes a pharmaceutically acceptable diluent or carrier, and inherently other optional elements of said pharmaceutical composition, and a second dosage form a first dosage form that also includes a pharmaceutically acceptable diluent or carrier, and inherently other optional elements of said pharmaceutical composition.

Therefore, this rejection of Claim 5, for lack of clarity, is not proper and should be withdrawn.

Conclusion

In view of the above, Applicant respectfully submits that the Examiner's rejections under 35 USC 112, first paragraph and 35 USC 112, second paragraph of the pending claims, as amended, are not proper. Therefore, Applicant respectfully requests that these rejections of the pending claims, as amended, be withdrawn. Applicant further requests that a notice of allowance be issued for the pending claims as presently amended.

Respectfully Submitted:

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